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Dated: May 27, 2005 Signature: _____

(Danielle L. Herritt)

Docket No.: BSZ-050
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Raphael J. Mannino *et al.*

Application No.: 10/822230

Confirmation No.: 1325

Filed: April 9, 2004

Art Unit: 1636

For: NOVEL ENCOCHLEATION METHODS,
COCHLEATES AND METHODS OF USE

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. A copy of each reference on the PTO/SB/08 is attached.

Documents A19, A34, and D5 of the attached SB/08 were cited in an International Search Report issued October 22, 2004, during the prosecution of international application no. PCT/US2004/011026, which corresponds to the above referenced application. In accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), Applicant hereby submit(s) these documents for the Examiner's consideration. A copy of the International Search Report and of each document required under 37 CFR 1.98(a)(2) cited thereon are enclosed as well. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information

Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

In addition, Applicant directs the Examiner's attention to the following United States patent applications.


U.S. Ser. No.	Filing Date
11/042,598 (008DVCN)	01/24/05
11/040,615 (009CPCN2)	01/18/05
10/304,567 (010CN)	11/26/02
10/701,364 (014)	11/03/03
10/759,381 (017)	01/15/04
11/051,562 (038)	02/03/05
11/047,373 (039)	01/28/05
10/822,235 (049)	04/09/04

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. BSZ-050. A duplicate copy of this paper is enclosed.

Dated: May 27, 2005

Respectfully submitted,

By 
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Attorney/Agent For Applicant



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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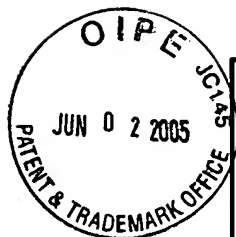
Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	BSZ-050

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	4,078,052	03-07-1978	Papahadjopoulos	
	A2	4,698,327	10-06-1987	Nagarajan <i>et al.</i>	
	A3	4,725,442	02-16-1988	Haynes	
	A4	4 871 488	10-03-1989	Mannino <i>et al.</i>	
	A5	4,874,795	10-17-1989	Yesair	
	A6	4,906,476	03-06-1990	Radhakrishnan	
	A7	4 990 291	02-05-1991	Schoen <i>et al.</i>	
	A8	5,026,557	06-25-1991	Estis <i>et al.</i>	
	A9	5,100,591	03-31-1992	Leclef <i>et al.</i>	
	A10	5 269 979	12-14-1993	Fountain	
	A11	5,409,698	04-25-1995	Anderson <i>et al.</i>	
	A12	5,484,589	01-16-1996	Saiganik	
	A13	5,571,517	11-05-1996	Yesair	
	A14	5,580,859	12-03-1996	Feigner <i>et al.</i>	
	A15	5,589,466	12-31-1996	Feigner <i>et al.</i>	
	A16	5 643 574	07-01-1997	Gould - Fogerite <i>et al.</i>	
	A17	5,834,015	11-10-1998	Oleske <i>et al.</i>	
	A18	5,840,707	11-24-1998	Mannino <i>et al.</i>	
	A19	5,994,318	11-30-1999	Gould - Fogerite <i>et al.</i>	
	A20	6,120,751	11-19-2000	Unger	
	A21	6,153,217	11-28-2000	Jin <i>et al.</i>	
	A22	6,340,591	01-22-2002	Margolis <i>et al.</i>	
	A23	6,403,056	06-11-2002	Unger	
	A24	6,406,713	06-18-2002	Janoff <i>et al.</i>	
	A25	6,447,800	09-10-2002	Hope	
	A26	6,592,894	07-15-2003	Zarif <i>et al.</i>	
	A27	6,808,720	10-26-2004	Unger	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	A28	FR 2 221 122 A	10-11-1974	Bayer AG		Abstract
	A29	EP 435 503 A1	07-03-1991	Eli Lilly and Co.		
	A30	EP 667 353 A1	08-16-1995	Eli Lilly and Co.		
	A31	WO 96 25942	08-29-1996	Albany Medical College <i>et al.</i>		
	A32	WO 97 30725	08-28-1997	Mannino <i>et al.</i>		
	A33	WO 00 42989	07-27-2000	Biodelivery Sciences, Inc. <i>et al.</i>		
	A34	WO 01 52817	07-26-2001	Biodelivery Sciences, Inc. <i>et al.</i>		
	A35	WO 04 012709	02-12-2004	Jin		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	BSZ-050

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	B1	ANDERSON, <i>et al.</i> Formulation and evaluation of a folic acid receptor-targeted oral vancomycin liposomal dosage form. <i>Pharm Res</i> 18(3): 316-22, 2001.	
	B2	ARNDT, <i>et al.</i> Liposomal bleomycin: increased therapeutic activity and decreased pulmonary toxicity in mice. <i>Drug Deliv</i> 8(1): 1-7, 2001.	
	B3	ASAI, "Formation of the dispersed particles composed of retinol and phosphatidylserine," <i>Int J Pharm</i> , 253: 89-95, 2003.	
	B4	AVILES, <i>et al.</i> Pegylated liposomal doxorubicin in combination chemotherapy in the treatment of previously untreated aggressive diffuse large-B-cell lymphoma. <i>Med Oncol</i> 19(1): 55-58, 2002.	
	B5	BOOSER, <i>et al.</i> Anthracycline antibiotics in cancer therapy. Focus on drug resistance. <i>Drugs</i> . 47(2):223-58, 1994.	
	B6	COUVREUR, <i>et al.</i> Nano- and microparticles for the delivery of polypeptides and proteins. <i>Adv. Drug Delivery Rev</i> , 10: 141-162, 1993.	
	B7	CREUZENET, <i>et al.</i> Interaction of alpha s2- and beta-casein signal peptides with DMPC and DMPG liposomes. <i>Peptides</i> , 18(4): 463-472, 1997.	
	B8	DERES, <i>et al.</i> <i>In vivo</i> priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine. <i>Nature</i> . 342(6249):561-4, 1989.	
	B9	FINBERG, <i>et al.</i> The induction of virus-specific cytotoxic T lymphocytes with solubilized viral and membrane proteins. <i>J Exp Med</i> . 148(6):1620-7, 1978.	
	B10	GEMMELL, <i>et al.</i> Comparative effects of drugs on four paw oedema models in the rat. <i>Agents Actions</i> . 9(1): 107-116, 1979.	
	B11	GOODMAN-SNITKOFF, <i>et al.</i> The glycoprotein isolated from vesicular stomatitis virus is mitogenic for mouse B lymphocytes. <i>J Exp Med</i> 153: 1489-1502, 1981.	
	B12	GOODMAN-SNITKOFF, <i>et al.</i> Defining minimal requirements for antibody production to peptide antigens. <i>Vaccine</i> . 8(3):257-62, 1990.	
	B13	GOODMAN-SNITKOFF, <i>et al.</i> Role of intrastructural/intermolecular help in immunization with peptide-phospholipid complexes. <i>J Immunol</i> . 147(2):410-5, 1991.	
	B14	GOULD-FOGERITE, <i>et al.</i> Chimera-mediated gene transfer in vitro and in vivo. <i>Gene</i> . 84(2):429-38, 1989.	
	B15	GOULD-FOGERITE, <i>et al.</i> Rotary dialysis: its application to the preparation of large liposomes and large proteoliposomes (protein-lipid vesicles) with high encapsulation efficiency and efficient reconstitution of membrane proteins. <i>Anal Biochem</i> . 148(1):15-25, 1985.	
	B16	GOULD-FOGERITE, <i>et al.</i> The reconstitution of biologically active glycoproteins into large liposomes: use as a delivery vehicle to animal cells. <i>Adv Memb Biochem Bioener</i> . 569-586, 1988.	
	B17	GOULD-FOGERITE, <i>et al.</i> Liposome preparation and related techniques. <i>Liposome Technology</i> , 2 nd Edition. 1:67-80, 1993.	
	B18	GOULD-FOGERITE, <i>et al.</i> Interaction of liposomes with the biological milieu. <i>Liposome Technology</i> , 2 nd Edition. 3:261-276, 1993.	
	B19	GOULD-FOGERITE, <i>et al.</i> "Mucosal and systemic immunization using cochleate and liposome vaccines" <i>J. Liposome Res</i> , 6(2): 357-79, 1996.	
	B20	GOULD-FOGERITE <i>et al.</i> , "Targeting immune response induction with cochleate and liposome-based vaccines" <i>Adv Drug Delivery Rev</i> , 32(3), pgs. 273-287, 1998.	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/822230-Conf. #1325
				Filing Date	April 9, 2004
				First Named Inventor	Raphael J. MANNINO
				Art Unit	1636
				Examiner Name	Not Yet Assigned
Sheet	3	of	4	Attorney Docket Number	BSZ-050

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	C1	GOULD-FOGERITE, et al. Cochleates for induction of mucosal and systemic immune responses. <i>Meth Molec Med</i> 42: 179-196, 1999.		
	C2	GOULD-FOGERITE, et al., Cochleate Delivery Vehicles: Applications in Vaccine Delivery. <i>J Liposome Res</i> , 10(4): 339-358, 2000.		
	C3	HALE, et al. Elicitation of anti-Sendai virus cytotoxic T lymphocytes by viral and H-2 antigens incorporated into the same lipid bilayer by membrane fusion and by reconstitution into liposomes. <i>J Immunol.</i> 124(2):724-31, 1980.		
	C4	JIN, U.S. Patent Application Publication No. 2004/0092727, published 05-13-2004.		
	C5	LAVELLE, et al. Improved methods for the delivery of liposome-sequestered RNA into eucaryotic cells. <i>Arch Biochem Biophys.</i> 215(2):486-97, 1982.		
	C6	LICHTENBERG, et al. Liposomes: Preparation, Characterization and Preservation. <i>Meth Biochem Anal.</i> 33:337-462, 1988.		
	C7	LONGENECKER, et al. Three dimensional structure of mammalian casein kinase I: Molecular basis for phosphate recognition. <i>J Mol Biol</i> , 257: 618-631, 1996.		
	C8	MANNINO, et al. Liposome mediated gene transfer. <i>Biotechniques.</i> 6(7):682-90, 1988.		
	C9	MANNINO, et al. Liposomes as adjuvants for peptides: Preparation and use of immunogenic peptide-phospholipid complexes. <i>Liposome Technology</i> , 2 nd Edition. 2:167-184, 1993.		
	C10	MANNINO, et al. Lipid matrix-based vaccines for mucosal and systemic immunization. <i>Pharm Biotechnol.</i> 6:363-87, 1995.		
	C11	MANNINO, et al. Antigen cochleate preparations for oral and systemic vaccinations. <i>New Gen Vaccines</i> 2 nd ed., Ch 18, pgs. 229-39, 1997.		
	C12	MILLER, et al. Vaccination of rhesus monkeys with synthetic peptide in a fusogenic proteoliposome elicits simian immunodeficiency virus-specific CD8+ cytotoxic T lymphocytes. <i>J Exp Med.</i> 176(6):1739-44, 1992		
	C13	MORI, et al. Immunotargeting of liposomes containing lipophilic antitumor prodrugs. <i>Pharm Res.</i> 10(4):507-14, 1993.		
	C14	MORILLA, et al. Development and in vitro characterization of a benzimidazole liposomal formulation," <i>Int J Pharm</i> 249(1-2): 89-99, 2002.		
	C15	OSOBA, et al. Effect of treatment on health-related quality of life in acquired immunodeficiency syndrome (AIDS)-related Kaposi's sarcoma: a randomized trial of pegylated-liposomal doxorubicin versus doxorubicin, bleomycin, and vincristine. <i>Cancer Invest</i> 19(6): 573-80, 2001.		
	C16	PAPAHADJOPOULOS, et al. Cochleate lipid cylinders formation by fusion of unilamellar vesicles. <i>Biochim Biophys Acta.</i> 394(3): 483-491, 1975.		
	C17	PAPAHADJOPOULOS, et al. The use of lipid vesicles for introducing macromolecules into cells. <i>Prot Turnover Lysosome Funct.</i> 543-60, 1978.		
	C18	PARKER, et al. In vivo and in vitro antiproliferative effects of antisense interleukin 10 oligonucleotides. <i>Meth Enzym: Antisense Tech, Part B</i> 314: 411-29, 1999.		
	C19	SANDERSON, et al. Encapsulation of vancomycin and gentamycin with cationic liposomes for inhibition of growth of Staphylococcus epidermidis. <i>J Drug Target</i> 4(3): 181-89, 1996.		
	C20	SANTANGELO, et al. Efficacy of oral cochleate-amphotericin B in a mouse model of systemic candidiasis. <i>Antimicrob. Agents Chemother.</i> pgs. 2356-2360, 2000.		

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	D1	SUNDRAM, <i>et al.</i> General and efficient method for the solution- and solid-phase synthesis of vancomycin carboxamide derivatives. <i>J Org Chem</i> 60:1102-03, 1995.		
	D2	WASSEF, <i>et al.</i> Liposomes as carriers for vaccines. <i>Immunomethods</i> . 4(3):217-22, 1994.		
	D3	ZARIF, <i>et al.</i> , Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infection. <i>Proceedings of the International Symposium on Controlled Release of Bioactive Materials</i> , Illinois: Controlled Release Society, pgs. 964-965, 1999.		
	D4	ZARIF, <i>et al.</i> Antifungal activity of amphotericin B cochleates against <i>Candida albicans</i> infection in a mouse model. <i>Antimicrob. Agents Chemother</i> 1463-1469, 2000.		
	D5	ZARIF, <i>et al.</i> Cochleates: New lipid based drug delivery system. <i>J. Liposome Res</i> 10(4): 523-538, 2000.		
	D6	Zarif, <i>et al.</i> Elongated supramolecular assemblies in drug delivery. <i>J. Controlled Rel</i> 81: 7--23, 2002.		
	D7	International Search Report for Application No. PCT/US2004/011026.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Application No. (if known): 10/822230

Attorney Docket No.: BSZ-050

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**TRANSMITTAL
FORM**

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/822230-Conf. #1325
	Filing Date	April 9, 2004
	First Named Inventor	Raphael J. MANNINO
	Art Unit	1636
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	BSZ-050

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<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): IDS (citation) by Applicant (References A26-D7 cited therein) Certificate of Mailing Return Receipt Postcard
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Signature			
Printed name	Danielle L. Herritt		
Date	May 27, 2005	Reg. No.	43,670

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Signature: (Danielle L. Herritt)